

WEEK ENDING SEPTEMBER 12, 2014

OPP Weekly Activity Report

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REGISTRATION DIVISION

New Tolerances Established for Tryfloxstrobin On September 3, 2014, the Federal Register published a final rule establishing tolerances for residues of the fungicide trifloxystrobin on dry pea seed and field pea hay and vines. Trifloxystrobin is a broad-spectrum fungicide that controls a variety of plant diseases in various fruit, nut, vegetables, and field crops for which tolerances currently exist, including livestock commodities, ranging from 0.01 to 38 ppm. Trifloxystrobin belongs to a chemical class of beta-methoxyacryl ester fungicides that are synthetic analogs of strobilurin A. Its fungicidal action occurs by interfering with respiration in plant pathogenic fungi. The site of action of strobilurin compounds is located in the mitochondrial respiration pathway in which trifloxystrobin is a potent inhibitor of fungal spore germination and mycelial growth. Primary target pests of trifloxystrobin include grape and cucurbit powdery mildew, apple scab and powdery mildew, peanut leafspot, and brown patch of turfgrasses. Concurrent with petitioning for new use tolerances, the registrant, Bayer, requested registration of the affected pending product, a suspended concentrate formulation which also contains the active ingredient, prothioconazole. (Sidney Jackson, 703/305-7610)

Planning Meeting for NAFTA Joint Reviews for Minor Uses On September 8, 2014 Barbara Madden of the Registration Division (RD) Minor Use Team met with representatives of Canada's Pesticide Management Regulatory Agency (PMRA) and Agriculture and Agri-Food Canada (AAFC) Pest Management Centre (PMC) as well as members of Interregional Research Project Number 4 (IR-4) to discuss the ongoing NAFTA Joint Review/Workshare Projects for Minor Uses and to identify projects to be submitted during FY 2015. EPA and PMRA completed work on 6 actives/13 crops as joint review projects during FY14. Currently, there are joint review projects pending for six chemicals for metrafenone (cherry, hops, cantaloupe, squash, and peach), sethoxydim (blueberry), metconazole (sunflower), prohexadione calcium (strawberry), s-metolachlor (cantaloupe and summer squash), and pyrimethanil (GH cucumber). Additional projects for 14 active ingredients were identified at the planning meeting for possible submission during FY 2015 (Barbara Madden, 703/305-6463).

RD (Lois Rossi, Barbara Madden, and Sidney Jackson) participated in the annual Interregional Research Project Number 4 (IR-4) Food Use Workshop during September 9 and 10, 2014. IR-4 develops residue field trial data for projects based on requests from growers, grower groups, and State/Federal Research and Extension Agents. Each year IR-4 receives considerably more requests for projects than there are resources to conduct residue field trial studies. Therefore, stakeholders (growers, grower groups, and State/Federal Research and Extension

Agents) meet annually to discuss the potential researchable projects and prioritize what projects will be worked on in the next growing season. At the beginning of the 2014 workshop Jerry Baron, Executive Director of IR-4 presented Lois Rossi, RD Director with a plaque and announced her induction into the IR-4 Hall of Fame for all the work she has done on behalf of specialty crop and minor use growers. Barbara Madden made a presentation to provide the audience updates on various topics, including crop grouping, pollinators concerns, criteria for the public interest finding for the IR-4 fee exemption, resistance concerns for antibiotics, NAFTA joint reviews, and the grower priority database. Representatives from most chemical companies were also present and provided the audience an update on the pesticide chemicals under consideration at the workshop and new chemistries in the development stages. The meeting was well-attended with a record number of participants this year. There were some lively discussions regarding the needs of growers for efficacious tools. (Barbara Madden, 703/305-6463)

RD Participates in First IR-4 Biopesticide Workshop At the end of the 2014 IR-4 Food Use Workshop, IR-4 then sponsored the first ever Biopesticide Workshop held on September 10, 2014 in Atlanta, Georgia. Members of RD (Lois Rossi, Barbara Madden, and Sidney Jackson) participated in this workshop representing the Office of Pesticide Programs. There were several speakers that made presentations on their ongoing research on possible biopesticide tools for many of today's major pest problems in agriculture. The audience heard about possible biopesticide controls for citrus greening and citrus psyllid, the insect that transmits the greening disease. There was also a report on some promising research for a biopesticide control of fire blight, an important disease in fruit production. This will be especially important in 2015 when organic fruit growers will no longer be able to use antibiotics in organic production. Additionally, there was a discussion on research of trap and kill bait stations for the Brown Marmorated stink bugs which would include the use of a pheromone to attract the stink bug and use of an insecticide to kill the stink bug once trapped. (Barbara Madden, 703/305-6463)

Registration Division Participates in Antibiotic Summit

On September 11, 2014, an Antibiotic Summit was held in Atlanta, Georgia to discuss the issues surrounding the use of antibiotics in crop production to control bacterial diseases. Susan Jennings, Public Health Coordinator of OPP, made a presentation on the regulatory review process and Shaunta Hill of RD discussed the recent regulatory decision for the registration for kasugamycin. There were also presentations made by university researchers from various states who reported that use of antibiotics such as streptomycin, oxytetracycline, and kasugamycin are important tools to control bacterial diseases such as citrus greening, fire blight, zebra chip, bacterial canker, walnut blight and leaf spot in fruit, tree and field crops. Presentations were made by Dr. Jean B. Patel, Deputy Director, Office of Antimicrobial Resistance Centers for Disease Control and Prevention of the CDC and Dr.

Heather C. Harbottle, Microbiologist, Division of Animal of Food and Microbiology, Food and Drug Administration to discuss considerations undergone in addressing the use antibiotics for agricultural uses and FDA's *Guidance to Industry #152* document and its intent on persevering antibiotic drugs important for treating human disease. (Barbara Madden, 703/305-6463)

Section 18 Authorized for Use of Sulfoxaflor on Sorghum On September 11, 2014, EPA authorized a Section 18 Emergency Exemption to the Georgia Department of Agriculture and the Missouri Department of Agriculture for the use of sulfoxaflor on sorghum to control sugarcane aphid. Unusually high populations of aphids are causing direct plant death from aphid feeding as well as indirect damage and harvesting issues from the aphid honeydew residue. This pest situation could be potentially disastrous for the 2014 growing season. The Section 18 authorizations expire November 30, 2014. (Keri Grinstead, 703/308-8373)

New Tolerance Established for Sulfentrazone On September 12, 2014, the Federal Register published a final rule establishing a tolerance for residues of sulfentrazone in or on apple. The mode of action for sulfentrazone, an herbicide used to control a variety of broadleaf weeds, is by protoporphyrinogen oxidase (PPO) inhibition. In effect, plants emerging from soils treated with sulfentrazone turn necrotic and die shortly after exposure to light. FMC Corporation owns the pesticide product labeling associated with this action, and the Interregional Research Project No.4 (IR-4) petitioned the Agency for these new uses. (Laura Nollen, 703/305-7390)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)						
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date	
The Fungicide Branch granted:						
Fluensulfone	Makhteshim Chemical Works Ltd.	11678-73	R10	9/28/2014	9/11/2014	
Jennifer Gaines, 703/305-5967						
Ethephon	Tenkoz Inc.	55467-16	R300	9/23/2014	9/10/2014	
Craig Reeves, 703/347-0486						
Trifloxystrobin	Bayer CropScience LP Bayer Environmental Science	264-777 264-781 264-1054 432-1371	R350	1/2/2015	9/5/2014	
Triadimefon	Bayer Environmental Science		R350	1/2/2015	9/5/2014	
Mepiquat chloride	Mepiquat chloride Drexel Chemical Company		R351	10/3/2014	9/5/2014	
Shaunta Hill, 703/347-8961						
Piperalin	SePro Corporation	67690-7	R351	10/3/2014	9/10/2014	

	Erin Malone, 703/347-0253					
The Herbicide Branch gra	anted:					
Pyroxasulfone	FMC Corporation Agricultural Products Group	279-3468	R310	9/22/2014	9/10/2014	
MCPA, dimethylamine salt	PBI/Gordon Corp	2217-994	R310	9/25/2014	9/10/2014	
Clodinafop-propargyl	Syngenta Crop Protection, LLC	100-909 R351		9/24/2014	9/10/2014	
Bethany Benbow, 703/347-8072						
Trifluralin	Agan Chemical Manufacturing, Ltd.	11603-13	R351	10/6/2014	9/10/2014	
Shanta Adeeb, 703/347-0502						
The Insecticide Branch granted:						
Methoxyfenozide	Dow AgroSciences LLC	62719-437 62719-442	R170	9/8/2014	9/8/2014	
	Olga Odiott, 703/308-9369					
Fipronil	Control Solutions, Inc.	53883-351 53883-352	R300	9/30/2014	9/9/2014	
Carlyn Petrella, 703/347-0439						
d-Allethrin	The Schawbel Corporation	71910-2	R340	9/8/2014	9/8/2014	
Carmen Rodia, 703/306-0237						
The Insecticide-Rodentic	ide Branch granted:					
Fluensulfone	luensulfone Makhteshim Agan of North America, Inc,		R10	9/29/2014	9/11/2014	
Jennifer Gaines, 703/305-5967						

PRIA Categories

R10 – New active ingredient, food use⁽²⁾ (3); R170 – Additional food use; R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix (3) (4); R310 – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging (2) (3); R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements) (2) (3); R350 – Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) (2) (3); and R351 – Amendment adding a new unregistered source of an active ingredient (2) (3).

Registration Actions Granted Under FIFRA Section 18 Emergency Exemptions							
State/Federal	Chemical	Product Name	Crop/Site	Pest	Authorization		
Agency	Emergency	EPA Reg/			Date		
	Exemption Number	File Symbol					
Specific Exemption(s)							
Georgia	Sulfoxaflor	Transform® WG	Sorghum	Sugarcane	9/11/2014		
	(14-GA-04)	(62719-625)	Jorgilain	aphid	7/11/2014		
Missouri	Sulfoxaflor	Transform® WG	C = = == =	Sugarcane	0/11/0014		
	(14-MO-02)	(62719-625)	Sorghum	aphid	9/11/2014		
Keri Grinstead, 703/308-8373							

ANTIMICROBIALS DIVISION

Antimicrobials Division Hosts Conference Call with CDC on the Enterovirus D68 (EV-D68): September 10, 2014, AD and BEAD held a teleconference with the CDC to discuss the emerging issue presented by EV-D68. Recently, a pediatric hospital in Kansas City, MO has experienced over 300 cases of respiratory illnesses in their facility. Approximately 15% of those illnesses have resulted in children being placed in an intensive care unit. Testing of specimens from several cases at a specialized laboratory at the CDC indicated that 19 of the 22 specimens were positive for EV-D68. The St. Louis area is also experiencing a recent increase in pediatric respiratory illnesses. EPA and CDC have a MOU for addressing emerging pathogens including the implementation of a viral disinfection hierarchy when necessary. The discussions focused on the development of criteria for determining which registered disinfectant products would be most likely to inactivate EV-D68 on hard, non-porous surfaces in order to be prepared to respond rapidly, if needed, as the situation with this emerging pathogen continues to develop. (Emily Mitchell, 703-308-8583)

FIELD & EXTERNAL AFFAIRS DIVISION

GAO Audit on Chemical Assessments. This audit investigated five agencies – Agency for Toxic Substances and Disease Registry, EPA (ORD was lead program for audit), National Institute for Occupational Safety and Health, National Toxicology Program, and the Occupational Safety and Health Administration – and 10 states to gauge their ability to coordinate activities with regard to conducting chemical assessments. GAO had no recommendations for EPA, and OPP has no comments on the final draft report. The final report is due to be published in November of this year. (Cameo Smoot, 305-5454)

FEAD Presents on Pesticide Packaging to Manufacturers. On September 10, Nancy Fitz of participated in a panel discussion about current regulatory policies and trends for pesticide packaging at the Specialty and Agro Chemicals America 2014 conference in Charleston, SC. The conference is attended by pesticide and specialty chemical manufacturers, formulators, toll manufacturers and repackagers. Approximately 150 people attended the panel discussion, which also included Scott Birchfield of Syngenta Crop Protection and was moderated by Allen Bartlo of Bartlo Packaging, Inc. Nancy discussed some basic principles of FIFRA, the pesticide container regulations and supplement distribution and how those three areas overlap. (Nancy Fitz, 305-7385)

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

<u>BEAD Meets with Methyl Bromide Critical Use Exemption Consultants</u>. David Riggs and James Schaub met with BEAD to discuss their forthcoming submission to request critical use exemptions (CUE) on behalf of the Golf Course

Superintendents and the Cut Flower industries for use in 2017. Among the topics of discussion were the content of previous applications on behalf of these sectors and reasons why they were not included in recent US nominations. (Bill Chism, 703 308-8136; Andrew Lee, 703 308-7226; Colwell Cook, 703 308-8146; and David Donaldson, 202 343-9086)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

OPP FOIA Request Status Report for Sept 1- 5, 2014							
	equests ceived	Requests Closed Requests Open			ts Open		
FY14	This Week	FY14	FYTD	This Week	FY14	Prior Years	Total
501	15	312	420	14	189	214	403

(Ana Espinoza, 703-347-0102)

Environmental Chemistry Methods (ECM) Index Updated. The ITRMD Web Team worked with EFED to update the ECM Index tables with the Environmental Chemistry Method, Independent Laboratory Validation (ILV) and EPA Review for the following chemicals: Iodomethane, Saflufenacil, Tolfenpyrad, Imazosulfuron, Indaziflam, Flutriafol, Mandipropamid, Benfluralin, Benomyl, Bensulfuron-methyl, and Triazines. For more information, please visit http://www.epa.gov/pesticides/methods/ecm-2.html. (Miriam Organic, 703-605-0583; Christine Tran, 703-305-1577)

BIOPESTICIDES & POLITION PREVENTION DIVISION

BPPD Participates in the National Potato Council EPA Summer Tour. From August 26-27, BPPD participated in an OPP crop tour to southern New Jersey and eastern Pennsylvania to visit Jim Coombs Farm, Seabrook Brothers and Sons packing Facility, Rutgers Agricultural Research and Extension Center, Herr's Potato Chip Plant, and Herr's Beef Cattle Operation. It was a great opportunity to interact with local potato farmers, crop service providers, university researchers, extension specialists, potato chip manufacturing operators, and representatives from the National Potato Council. Presentations included topics such as potato production, integration of technology into farming practices and equipment, and crop pest management. The importance of the interdependent relationships between growers, crop service providers, manufacturing vendors, and Ag extension specialists was heavily emphasized. Several discussions were held on a large variety of agricultural challenges, and it was evident that there was very limited research and practice of integrated pest management and biopesticide

use at the sites visited due to the magnitude of the pest problems. Overall, the tour provided informative insight into advances in conventional farming practices, current research in commercial agriculture, and the urgent need for more effective crop management practices and outreach for use of biopesticides in IPM. (Elyse Lee 703-347-0633).

Brazilian Company Presents Biofertilizer to BPPD Staff On September 8, representatives from Microbiol, a Brazilian agricultural company, presented information to BPPD on Microgeo, a biological fertilizer sold and used in Brazil since 2006. Microbiol was assisted in its presentation by AMCHAM Brazil, a Brazilian chamber of commerce that supports Brazilian companies in their relations with United States companies and government agencies. Although Microgeo is marketed as a fertilizer and not as a pesticide, the product's technical manual claims improvements in soil restoration and plant health. The product is sold as a compost that is mixed at the use site with cattle manure and water in a large tank to produce a biofertilizer. Then the biofertilizer is applied directly to the soil of or as a foliar spray on a wide variety of crops. This product, if required to be registered as a plant growth regulator under FIFRA, would present a novel use pattern. BPPD is consulting with EPA's Office of General Counsel to make such a determination. (Michael Glikes, 703-305-6231)

BPPD Attends Plant Genome Research Program Awardees Meeting From September 4-5, BPPD attended the National Science Foundation (NSF) Plant Genome Research Program 17th Annual Awardees Meeting. The National Plant Genome Initiative (NPGI) Research Program was first established back in 1998, and NSF's long-term research initiative is aimed at gaining more insight into the structure and function of genomes. Presentation topics included biochemical genomics, training the next generation of scientists, and describing the National Plant Genome Initiative – The Next 5-Year Plan. Synthetic biology was discussed and a presentation on engineering a synthetic centromere for artificial chromosome segregation in maize was given. The NPGI is managed by the Interagency Working Group on Plant Genomes of the National Science and Technology Council. BPPD's Kenneth Haymes is a member of this workgroup. (Kenneth M. Haymes, 703-347-0398).

ENVIRONMENTAL FATE & EFFECTS DIVISION

Scientists Participate in 10th Bilateral Meeting with Japan's Ministry of Environment. On September 9th and 10th, EFED scientists met with their counterparts from Japan's Ministry of Environment (MoE) to complete draft guidelines for the testing of potentially endocrine-active substances in fish and frog. The meeting was hosted by OCSPP's Office of Science Coordination and Policy. In coming weeks, the draft test guidelines will be submitted to the Organization for Economic Cooperation and Development (OECD) for review. The Medaka Multi-generation

Test and Larval Amphibian Growth and Development Assay were developed through a multi-year partnership between US EPA and Japan's MoE. Both tests were reviewed by EPA's FIFRA Scientific Advisory Panel (SAP) last year. The draft OECD test guidelines are based largely on EPA's internal drafts of guidelines that will become part of the Endocrine Disruptor Screening Program (EDSP) Series 890. Participants in the bilateral meeting reconciled differences among the OECD and USEPA draft versions and incorporated technical advice from the SAP, including recommendations for tracking and minimizing the occurrence of scoliosis ("bent tail") in amphibian assays with the African clawed frog (Xenopus laevis). (Catherine Aubee, 703-347-8029; Ed Scollon, 703-305-1333).

HEALTH EFFECTS DIVISION

Region 10 Spray Drift Issue & Oregon Coastal Non-point Source Protection

<u>Program:</u> A call was held on 9/8/14 with Linda Liu of Region 10 to discuss issues which have arisen related to the approval of Oregon's Coastal Non-point Source Protection Program. This program contains many elements, most of which are not related to pesticides. One issue which has arisen is related to the use of herbicides in forestry and how this is considered in risk assessment. Specifically Region 10 had questions regarding how inhalation exposures are considered in the process. Information was provided which details the current effort to develop a spray drift policy for human health risk assessment (e.g., draft policy and docket information). Additionally, there was discussion about how drift from forestry uses of herbicides will be accounted for when responding to the public comments on that policy. (Jeff Dawson, 305-7329).

Meeting with Region 9 & California Ag Commissioners on Spray Drift Research Program: A meeting was held on 9/9/14 with California Ag Commissioners, Region 9 staff and senior level OPP managers. The agenda for the meeting addressed several topics including pollinators and worker health and safety. The majority of the meeting, however, was spent discussing the implications surrounding an upcoming research project being conducted by Region 9 in collaboration with ORD intended to develop a method for sampling exposures from spray drift in schools. Several points were raised by the Ag Commissioners including access to the sampling events themselves, the potential implications of any possible results which includes a high degree of Congressional interest, possible impacts on local agricultural economies in California, the lack of rigor in the testing program especially regarding school site selection, and how the resulting communication strategy would or would not include regional staff. (Jeff Dawson, 305-7329)

<u>Toxicology Meeting with Japanese Visitors:</u> Elizabeth Mendez, Anna Lowit, and Monique Perron met with several visitors from Japan on Friday, September 5th. The

agenda included topics related to toxicology and human health hazard assessment such as review and interpretation of DNT guideline studies, particularly for the neonicotinoids; smart testing approaches for DNT; requirement of only the sub-chronic dog study; science policies on liver toxicity and plasma cholinesterase; and acceptance of the extended one-generation reproductive toxicity study. It was a productive meeting; OPP offered support to the Japanese scientists in their efforts to revise/refine Japanese science policies. (Anna Lowit, 308-4135)

FCID Website Update Now Live (http://fcid.foodrisk.org/): Over the course of several months, CEB has worked with the University of Maryland's Joint Institute for Food Safety and Nutrition (JIFSAN) in updating the Food Commodity Intake Database (FCID) to incorporate food consumption data from the 2005-2010 cycles of the CDC/NHANES "What We Eat In America" (WWEIA) survey. The previous version of FCID contained food consumption data from the 2003-2008 WWEIA survey cycles which is presently incorporated into the current version of our DEEM (Dietary Exposure Evaluation Model) dietary exposure software. The webpage, http://fcid.foodrisk.org/, provides an easy-to-use interface to search food recipes as well as a calculator to provide commodity consumption estimates. The (raw) database files are also available from the website for users to conduct additional, more complex queries and statistical analyses. Additional features on the website include: the ability to access and query the site using touch-screen devices such as Window 8 and Apple iPad products; the ability to now query for direct (instead of just indirect) water consumption; updated and now current crop groupings; and an updated/enhanced FAQ section. The updated NHANES/WWEIA 2005-2010 food consumption data now available at the JIFSAN website will also soon be incorporated into the next release of DEEM FCID for 2005-2010. (Matt Crowley, 305-7606)

OPP Meets with USDA on MRLdatabase.com: On September 10th, several staff from HED, RD, and OPP's Immediate Office met with representatives from USDA's Foreign Agricultural Service (FAS) to discuss the status of MRLdatabase.com (www.mrldatabase.com) – a website, funded jointly by EPA and USDA, that maintains U.S. and foreign pesticide (and veterinary drug) MRL/tolerance information and provides a user interface to allow for quick and easy queries by commodity, active ingredient, and/or market. The joint funding (via a USDA grant) expires in December 2014, but all parties recognize the benefit the website provides not just for EPA and USDA regulators but also federal and state enforcement agencies, U.S. growers, and domestic and foreign importers and exporters. The discussion focused on steps that can be made to continue funding, including the potential for a more formal contract to maintain the website. (Matt Crowley, 305-7606)

Meeting with Dow AgroSciences on Sulfoxaflor New Uses: Staff from HED and RD met with Dow AgroSciences (DAS) to discuss issues associated with HED's review of a number of new uses for the insecticide. The teleconference was held to clarify translation of residue data between various commodities, as well as harmonization of livestock commodity tolerances. Based on the discussion and materials submitted by DAS, HED's review can move forward. (William T. Drew, 305-3434; Christina Swartz, 305-5877; Elizabeth Holman, 603-8761)